

REMARKS

The above Amendments and these Remarks are in reply to the Advisory Action mailed August 29, 2007.

On August 23, 2007, in response to the final Office Action mailed 23 February 2007, Applicants filed a Notice Of Appeal, an Amendment/Response Under 37 C.F.R. §1.116, and Declarations of the two Inventors under 37 CFR 1.131(b).

The Advisory Action mailed August 29, 2007 enters the declarations, and makes a number of points why the Examiner does not believe them sufficient to antedate the Briegs reference.

The present Response G responds to the Examiner's points, and also submits two new Declarations Under 37 CFR 1.131(b) to provide even more evidence of sufficiently early conception and extensive and continuous diligence toward both actual and constructive reduction to practice throughout the required period. An RCE is also submitted herewith.

No fee is due for the addition of any new claims. An appropriate request for extension of time is being electronically submitted herewith.

Claims 1-5, 8-11, 139 and 140 were pending in the Application prior to the outstanding Office Action. In the Office Action, the Examiner rejected all pending claims. The present Response makes no changes to the claims. Reconsideration of the rejections is requested.

I. REJECTION OF CLAIMS 1-5, 8-11, 139 AND 140 UNDER 35 U.S.C. §103(a)

The Examiner rejected claims 1, 2, 4, 5, 8-11, 139 and 140 under 35 U.S.C. §103(a) as being unpatentable over Colon in view of Briegs U.S. Patent No. 7,054,823. The Examiner also rejected claim 3 under 35 U.S.C. §103(a) as being unpatentable over a combination of Colon, Briegs and Cimino.

As explained in Applicants' Response F, however, Briegs is not prior art, since its filing date did not precede the "date of the invention" by the inventors of the subject patent application. 35 U.S.C. §102(e).

Submitted herewith is a SECOND DECLARATION OF INVENTOR MICHAEL G. KAHN UNDER 37 C.F.R. §1.131(b), providing documentary evidence that the invention was conceived prior to September 10, 1999 (the filing date of the provisional application to which the Briegs patent claims priority), and that diligence toward reduction to practice existed from a date

prior to September 10, 1999, until after Applicants' constructive reduction to practice date of May 31, 2000 (Applicants' filing date).

Also submitted herewith is a SECOND DECLARATION OF INVENTOR MICHAEL MISCHKE-REEDS UNDER 37 C.F.R. §1.131(b) to the same effect.

Most of the two Second declarations parallel each other paragraph by paragraph and exhibit by exhibit. Therefore, for convenience, where a statement made herein is supported in both Second declarations in the same paragraph number(s) or exhibit letter(s), the indication of which declaration is being referenced will be omitted.

A. Conception

Both Second Declarations recite facts in paragraphs 3-21 sufficient to support conception of the invention as called for in claim 1.

Claim 1, as currently pending, calls roughly for a computer readable medium carrying a machine readable database identifying: (1) patient eligibility criteria for a clinical trial protocol; and (2) a plurality of workflow tasks for the clinical trial protocol. The workflow tasks are to include either (a) a post-enrollment instruction to have a specified test performed on the patient, or (b) a post-enrollment instruction to have a specified CRF completed for the patient. The inventors conceived of such a product well prior to September 10, 1999, the effective filing date of Briegs.

As evidence of this the inventors attach (1) a document entitled "FASTTRACK Systems, Inc. Execuctive (sic) Summary" (Exhibit A), which was dated August 10, 1999, and (2) screen shots from two non-functional demos in existence as of July 20, 1999, created under contract with FastTrack Systems (Exhibits B-H).

The Examiner is respectfully referred to the Second declarations themselves for the exact statements of the inventors and an explanation of what the exhibits A-H evidence. What follows here is a response to the objections made by the Examiner in the Advisory Action.

1. Dates Evidenced: Exhibit A

In the Advisory Action, the Examiner objects that "there is no date on the Executive Summary in Exhibit A."

Applicants submit that the date of Exhibit A, as being prior to the critical date of September 10, 1999, was sufficiently established in the original declarations. See, for example, MPEP 715.07(II), pointing out the propriety of blocking off dates in the exhibit and substituting an allegation in the declaration that the acts referred to occurred prior to a specified date.

Nevertheless, to remove all vestiges of doubt, the inventors have stated the actual dates throughout their Second declarations. Paragraph 5 of the Second declarations now recites:

The date of the document is not in the document itself, but the name of the document on disk is "FT Executive Smry 8_10_99.doc". Thus the date of this document is August 10, 1999, a month prior to September 10, 1999.

There can no longer be any doubt that conception, as evidenced by the Second declarations and corroborated by Exhibit A thereto, occurred no later than August 10, 1999, a month prior to September 10, 1999.

2. Dates Evidenced: Exhibits C-H

If Exhibit A is not enough, dates of conception are also established by the Second declarations with respect to Exhibits C-E, and also with respect to Exhibits F-H. These exhibits show screen shots generated by two software programs which existed prior to the critical date, and which show aspects of the invention as claimed.

In the Advisory Action, the Examiner objects that "Exhibit C is merely a screen shot". Applicants respectfully do not understand what is objectionable about a screen shot. A screen shot is merely a way to convert something that is rendered by a computer on a display, into something that can be attached to a declaration and submitted to the Office. It is not any less worthy as "evidence" than any other document.

The Examiner may be questioning the *date* evidenced by the screen shot, since it was prepared for purposes of Applicants' submission, not at the time of the original event.

In response, Applicants point out that the screen shot of Exhibit C (and that of Exhibits D and E as well), were generated by a version of the software ("SITE.exe") that has been unchanged since well prior to September 10, 1999. In particular, as now set forth in paragraph 11 of the Second declarations, the version of the software that was used to generate the screen shot has been unchanged since July 20, 1999.

As evidence that this version of the software has been unchanged since that date, the Second declarations attach Exhibit B, which is a screen shot of the directory listing of a folder on a FastTrack Systems CD-ROM. This directory listing shows "7/20/1999" as the "last-modified" date of the SITE.exe software. Second Declarations, para. 11.

Since the version of the program that was executed to generate the screen shots of Exhibits C-E was not modified since July 20, 1999, these screen shots show features that were present in the program as of that date. Second Declarations, para. 14.

Accordingly, it is respectfully submitted that the features evidenced by the screen shots of Exhibits C-E were conceived by the inventors at least as early as July 20, 1999, well prior to September 10, 1999.

Similarly, the screen shots of Exhibits F-H were generated by software ("SPONSOR.exe") that also has been unchanged since July 20, 1999. Second Declarations, paras. 11 and 18. Accordingly, it is respectfully submitted that the features evidenced by the screen shots of Exhibits C-E, too, were conceived by the inventors at least as early as July 20, 1999, well prior to September 10, 1999.

3. Nexus

In the Advisory Action, the Examiner argues that there is no clear nexus between the materials and the claimed subject matter. The Examiner says specifically that in paragraph 9 of the original declarations, the "role-specific task lists" recited in Exhibit A are not "equivalent" to a "specified test" as called for in the claim.

Initially, Applicants point out that the evidence of nexus is provided primarily by the testimony of the inventors, in the form of their written declarations. The exhibits are provided only to corroborate their testimony, amplifying it and confirming it. As pointed out in the MPEP:

"An accompanying exhibit need not support all claimed limitations, provided that any missing limitation is supported by the declaration itself. *Ex parte Ovshinsky*, 10 USPQ2d 1075 (Bd. Pat. App. & Inter. 1989)." MPEP 715.07(I), v8 rev6 (September 2007), p. 700-283, col. 2, 5th paragraph. (emphasis added).

Moreover, corroborating evidence is not even required in declarations under 37 CFR 1.131(b). See MPEP 715.07(I), v8 rev6 (September 2007), p. 700-285, bottom of col. 1, where 37 CFR 1.131(b) practice is being compared to interference practice:

"Also, in interference practice, conception, reasonable diligence, and reduction to practice require corroboration, whereas averments made in a 37 CFR 1.131 affidavit or declaration do not require corroboration; an applicant may stand on his or her own affidavit or declaration if he or she so elects. *Ex parte Hook*, 102 USPQ 130 (Bd. App. 1953)." MPEP 715.07(I), v8 rev6 (September 2007), p. 700-285, bottom of col. 1. (emphasis added).

Thus the Examiner's position that there is insufficient nexus between the "role-specific task lists" recited in an *exhibit* to the declaration, and the "specified test" as called for in Applicants' claim, is not relevant. What matters is the inventor's own testimony, which clearly says that the ICP database was to include "post-enrollment instructions to have a specified test performed on a patient", as called for in the claim.

Exhibit A further strengthens and confirms the inventors' testimony as set forth in the declarations. At a minimum, it confirms for the reader that the inventor is not basing his testimony entirely on memory. To accomplish this it is sufficient that the *inventor* recognizes the exhibit as confirming *for himself* that his memory is accurate. It is simply not relevant for this purpose that the words of the exhibit do not convey the claim language clearly *to an outsider* who does not have the benefit of knowing what the words meant to, and how they were used by, the people intimately involved in the activity at the time. *Cf. Brown v. Barbacid*, 436 F.3d 1376, 1382 (Fed. Cir. 2006) ("the Board erred in law, in failing to view the proffered evidence as it would be viewed by persons experienced in the field of the invention.")

In any event, in the Second Declarations submitted herewith, the two inventors have added the following statement: "I recall that the 'role-specific tasks' referred to in this statement included tasks which included performing specific tests on a patient, such as to draw blood for blood tests specified by the protocol for the current patient visit." Second Declaration Of Inventor Michael G. Kahn Under 37 C.F.R. §1.131(b), para. 9; and Second Declaration Of Inventor Michael Mischke-Reeds Under 37 C.F.R. §1.131(b), para. 9.

Thus if there was any doubt previously that the "role-specific tasks" referred to in Exhibit A of both Second Declarations, corroborates the inventors' memory that the iCP database referred to in the Exhibit was to include "post-enrollment instructions to have a specified test performed on a patient", such doubt is completely overcome by these further statements by the inventors.

In addition, the Examiner's objection completely ignores the evidence provided in paragraphs 11-21 of the declarations, and the accompanying exhibits B-H. These paragraphs and exhibits are themselves sufficient to establish conception of the entire invention prior to the critical date. These paragraphs and exhibits have been repeated in the inventors' Second declarations.

B. Diligence Toward Actual Reduction to Practice

Paragraphs 22-51 of The Second Declaration Of Inventor Michael Mischke-Reeds Under 37 C.F.R. §1.131(b) ("Second Declaration of Mischke-Reeds"), and paragraphs 22-31 of the Second Declaration of Inventor Michael G. Kahn Under 37 C.F.R. §1.131(b), both together with their accompanying exhibits, provide extensive proof of the inventors' diligence toward actual reduction to practice.

As described in this declaration, the process of developing a prototype began well before September 10, 1999. Roughly described, the process involved first developing a series of high level "use cases", setting forth a preliminary vision of what functions a system according to the invention would perform for a user. These preliminary "use cases" were prepared mainly by inventor Mischke-Reeds, together with others within FastTrack Systems. Second Declaration of Mischke-Reeds, paragraph 23.

Next, FastTrack Systems retained MONKEYmedia to help work through and refine the high level use cases, and develop a preliminary design for the graphical user interface (GUI). The development of the demo software described above was one of MONKEYmedia's deliverables, and was a necessary step in the ultimate development of a working prototype system. MONKEYmedia also worked on a Functional Specification which set out the detailed requirements that software programmers need to code the functional prototype. MONKEYmedia worked closely with the inventors continuously on these projects from about July 1999 through about July 2000. Second Declaration of Mischke-Reeds, paragraph 24.

Partially concurrently with MONKEYmedia's work, FastTrack Systems also engaged Concept Five Technologies, Inc., a software development firm, to develop the use cases and GUI design into a functional prototype system. Concept Five's process included drafting a software Architecture document, which divides the desired operation of the system into many functional components and specifies the ways that they are to interact in order to accomplish the desired operations. The Architecture document was developed and revised over numerous drafts. Concept Five also drafted technical specifications for many of the individual functional components, which is the next level of detail toward actual coding of the software. Concept Five worked closely with the inventors and FastTrack Systems continuously on these projects from about September 1999, well into 2000. Second Declaration of Mischke-Reeds, paragraph 25.

Beginning in January 2000, FastTrack Systems began hiring its own internal engineering team. Concept Five handed off the continued prototype development work to this team over a period of several months beginning in April 2000. Second Declaration of Mischke-Reeds, paragraph 26. The evidence shows that work by the internal engineering team continued at least through June 23, 2000, well after Applicants' filing date. Second declarations, para. 38.

In support of and as corroboration for the extensive and continuous diligence during the relevant period, the inventors attach numerous documentary exhibits to their Second declarations. These exhibits include, among other things:

- notebook pages evidencing status meetings with MONKEYmedia (Exhibit I);
- several documents prepared by MONKEYmedia during the course of their work (Exhibits C-H and K; Second Declaration of Mischke-Reeds, Exhibit R);
- a Functional Specification prepared by MONKEYmedia (Exhibit K);
- a notebook page evidencing the date that a particular member of the internal engineering team was hired (Exhibit L);
- a spreadsheet showing a plan for transitioning the development work over a period of months from Concept Five to the internal engineering team (Second Declaration of Mischke-Reeds, Exhibit Q);
- a collection of invoices from MONKEYmedia showing continuous engagement in the development work from at least as early as July 1999 through about July 2000 (Second Declaration of Mischke-Reeds, Exhibit N);

- a spreadsheet from Concept Five that was part of their proposal in August 1999 for performing the software development work (Second Declaration of Mischke-Reeds, Exhibit O);
- a Work Plan Summary prepared by Concept Five in October 1999 showing work done by Concept Five beginning no later than September 24, 1999, and projected to continue uninterrupted through at least December 6, 1999 (Second Declaration of Mischke-Reeds, Exhibit P) (in fact Mr. Mischke-Reeds recalls that Concept Five's engagement with FastTrack Systems began at least as early as September 22, 1999 and extended well into 2000);
- and three versions of the Architecture document being prepared and progressively refined by Concept Five, dated September 22, 1999, February 3, 2000, and February 22, 2000 (Second Declaration of Mischke-Reeds, Exhibits S, T and U).

Mr. Mischke-Reeds also points to specific language in many of the above documents which corroborate his recollection that the prototype being developed during the relevant period was to include a computer readable medium carrying a machine readable database having all the elements of claim 1: patient eligibility criteria for a clinical trial protocol, and workflow tasks for the clinical trial protocol, the workflow tasks including *both* a post-enrollment instruction to have a specified test performed on the patient, *and* a post-enrollment instruction to have a specified CRF completed for the patient. The Examiner is respectfully referred to the Second Declaration of Mischke-Reeds for details of this evidence.

As explained by the Federal Circuit in *Brown v. Barbacid*, 436 F.3d 1376 (Fed. Cir. 2006):

"Precedent requires that an inventor's testimony concerning his diligence be corroborated. See *Jolley*, 308 F.3d at 1328 ("corroboration is required to support an inventor's testimony regarding his reasonable diligence in pursuit of the invention"). Corroboration is determined by application of a rule of reason, for "corroboration of every factual issue contested by the parties is not a requirement of law." *Jolley*, 308 F.3d at 1328; see also *Price v. Symsek*, 988 F.2d 1187, 1196 (Fed. Cir. 1993) ("all of the evidence put forth" must be considered "as a whole, not individually" in evaluating whether the inventor's testimony is credible).

Unlike the legal rigor of conception and reduction to practice, diligence and its corroboration may be shown by a variety of activities, as precedent illustrates. The basic inquiry is whether, on all of the evidence, there was reasonably continuing activity to reduce the invention to practice. There is no rule requiring a specific kind of activity in determining whether the applicant was reasonably diligent in proceeding toward an actual or constructive reduction to practice." *Brown v. Barbacid*, 436 F.3d 1376, 1380 (Fed. Cir. 2006) (emphasis added).

Overall, the Second Declarations and their accompanying exhibits paint a picture of active and intensive development efforts throughout the critical period from before the effective date of Briegs (September 10, 1999) until after the filing of the subject patent application (May 31, 2000). Applicants respectfully submit that in light of the above standards for proving diligence, the Second Declaration of Mischke-Reeds and its accompanying exhibits amply prove the reasonable diligence of the inventors' efforts to reduce the subject invention to practice, during the entire period.

In the Advisory Action, the Examiner objects to the sufficiency of Applicants' original declarations for proving diligence on the ground that "The first date mentioned to establish diligence is 10/20/99".

Applicants respectfully submit that as set forth in the Second Declarations, the earliest date mentioned to establish *conception* is July 20, 1999, the last-modified date of software used to generate the screen shots of Exhibits B-H. Other documentation (not submitted herewith) may prove a date even earlier. The documents supporting *conception* at least as early as July 20, 1999, are equally effective to establish a date on which actual reduction-to-practice was proceeding diligently.

Accordingly, Applicants respectfully submit that sufficient diligence toward actual reduction to practice has been established.

C. Diligence Toward *Constructive* Reduction to Practice

In addition to diligence toward actual reduction to practice, Applicants also submit evidence showing diligence toward constructive reduction to practice as well. See paragraphs 23-33 of The Second Declaration Of Inventor Michael G. Kahn Under 37 C.F.R. §1.131(b) ("Second Declaration of Michael Kahn"), and the accompanying exhibits. There inventor Dr.

Kahn describes his efforts to select and retain a patent attorney, beginning at least as early as August 3, 1999, as corroborated by pages from his notebook (Second Declaration of Kahn, Exhibit N). Dr. Kahn also attaches a set of invoices from patent law firm Fliesler, Dubb, Meyer and Lovejoy, documenting their work in preparing the subject patent application from September 23, 1999 through the filing of the patent application on May 31, 2000. (Second Declaration of Kahn, Exhibit O).

Applicants submit that sufficient diligence toward constructive reduction to practice, as well, is established by Dr. Kahn's Second declaration.

* * * * *

Accordingly, it is respectfully submitted that Applicants have proven both conception of the subject invention as called for in claim 1, prior to the effective filing date of Briegs, as well as diligence toward both actual and constructive reduction to practice from a date prior to the effective filing date of Briegs until after the filing date of the subject patent application. As such, it is respectfully submitted that Briegs is not prior art and cannot, either by itself or in combination with any other reference, preclude patentability of Applicants' independent claim 1.

Claims 2-5, 8-11, 139 and 140 all depend ultimately from independent claim 1, and therefore should be patentable for at least the same reasons as claim 1. These claims also add their own limitations which, it is submitted, render them patentable in their own right. Applicants do not believe it necessary to address the substantive positions taken by the Examiner in rejecting any of the claims, but state for the record that they continue to disagree with the Examiner's positions and do not acquiesce in them.

Accordingly, claims 1-5, 8-11, 139 and 140 are believed to be patentable.

II. OTHER MATTERS AND CONCLUSION

In light of the above, it is respectfully submitted that all of the claims now pending in the subject patent application should be allowable, and a Notice of Allowance is requested. The Examiner is respectfully requested to telephone the undersigned if he can assist in any way in expediting issuance of a patent.

The fee required for a five-month extension of time under 37 C.F.R. § 1.136 is being electronically submitted herewith, extending the time to respond up to and including March 24, 2008. An RCE is also being submitted herewith, together with the required fee.

Fee Authorization. The Commissioner is authorized to charge any additional fee(s) that may be required in connection with this Response, or to credit any overpayment, to Deposit Account No. 50-0869 (FSTK 1000-0).

Respectfully submitted,

Date: 24 March 2008

By: /Warren S. Wolfeld/
Warren S. Wolfeld
Registration No. 31,454

HAYNES BEFFEL & WOLFELD LLP
P.O. Box 366
Half Moon Bay, CA 94019
Telephone: (650) 712 0340
Facsimile: (650) 712-0263